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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,668	09/13/2001	Jack Thacher Leonard	MCA-448 PC/US	8911
25182	7590	10/03/2005	EXAMINER	
MILLIPORE CORPORATION 290 CONCORD ROAD BILLERICA, MA 01821			MENON, KRISHNAN S	
		ART UNIT	PAPER NUMBER	
		1723		
DATE MAILED: 10/03/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/936,668	LEONARD, JACK THACHER	
	<b>Examiner</b>	<b>Art Unit</b>	
	Krishnan S. Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 24 August 2005.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1,2,4-6,11-16,18,22-25,27,32 and 33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 2,4,6,11-14,16,18 and 22 is/are allowed.

6)  Claim(s) 1,5,15,23-25,27,32 and 33 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

## DETAILED ACTION

Claims 1,2,4-6,11-16,18,22-25,27,32 and 33 are pending after the amendment of 8/24/05.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 15, 23,27,32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,223,133 (hereinafter referred to as Clark et al '133).

Clark et al '133 teach a process for concentration of nucleic acids (DNA samples – example) comprising the steps of providing ultrafiltration membrane (15) having a molecular cutoff between 100 D and 2000 kD and made of polysulfone in 25 multiple wells (11), processing a volume of up to 400 microliters, subjecting the sample on the membrane to vacuum (5) till nucleic acids are concentrated on the membrane (see figures 1-3, 6-7; col. 3, lines 15-18; col. 3, line 60 – col. 4, line 36; col. 5, lines 28-61). The filtration is at constant pressure, since the vacuum applied is a regulated external vacuum source (see col. 3, line 60 – col. 4, line 11), which does not vary during filtration. The biological material is recovered from the upstream side of the membrane as claimed (column 5 lines 33-36)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**2. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,223,133 (Clark et al; hereinafter referred to as Clark).**

Clark et al '133 teach a process for concentration of nucleic acids comprising the steps of providing ultrafiltration membrane (15) having a molecular cutoff between 100 D and 2000 kD and made of polysulfone in 25 multiple wells (11), processing a volume of up to 400 microliters i.e. 0 to 400 microliters of sample, subjecting the sample on the membrane to vacuum (5) till nucleic acids are concentrated on the membrane (see figures 1-3, 6-7; col. 3, lines 15-18; col. 3, line 60 – col. 4, line 36; col. 5, lines 28-61).

Re claim 24, the sample volume recited is about 500 microliters, where as Clark teaches up to 400 microliters. However, 400 microliters is not significantly off from "about 500 microliters". Also, Changes of size, shape, etc without special functional significance are not patentable. *Research Corp. v. Nasco Industries, Inc.*, 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; 43 USLW 3359 (1974)

Regarding claim 25, regulating the pressure differential to 169-914 millibars would be only optimizing the vacuum/pressure differential required for the filtration conditions. Clark teaches a regulated vacuum supply. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In

re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,223,133 (Clark et al; hereinafter referred to as Clark) in view of U.S. Patent No. 5,266,495 (hereinafter referred to as Lapidus).

Clark teaches all the limitations of claim 1. Instant claim adds the further limitation of a positive pressure of 5-80 psi, which Clark does not teach. Lapidus teaches constant positive pressure filtration (see figures and col 2 lines 56-66). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Lapidus in the teaching of Clark because Lapidus provides a method for controlled instrumented processing and quantitative information of the parameters during the filtration process (see col 1 lines 15-30).

#### ***Allowable Subject Matter***

Claims 2, 4, 6, 11-14, 16, 18 and 22 are allowed.

Reason for indicating allowable subject matter: The cited references do not teach subjecting a multiwell plate to a centrifugal ultrafiltration to a residue volume and then vacuum/pressure ultrafiltration to reduce the volume further to obtain the desired concentration of the material on the upstream side of the membrane.

***Response to Arguments***

Applicant's arguments filed 8/24/05 have been fully considered but are not persuasive regarding the rejected claims.

In response to the argument that Clark does not recover the retentate from the top surface of the membrane: This argument is contrary to the teaching of Clark. Clark teaches that the biological material is concentrated in the well, which would be on the top side (or upstream side) of the membrane. It is agreed that the Clark reference teaches removing the membrane using a transfer device, but the residue is still on the top or upstream side of the membrane. Removing the membrane is part of the residue recovery process. Claim recites recovering the residue from the upstream side, which is anticipated by the reference.

Argument re claim 28 is moot, applicant cancelled the claim.

Arguments re claim 25: the vacuum or pressure values can be optimized as discussed in the rejection. The retentate is recovered from the top of the membrane as shown above. Re the argument that Clark fails to suggest the process as being free of diafiltration, nowhere in the reference does Clark teach that diafiltration is required.

***Conclusion***

This action is made non-final because of the change in rejection of claim 24 from 35 USC 102(b) to 35 USC 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krishnan S. Menon  
Patent Examiner  
9/28/05